

## REMARKS

In the Office Action dated May 12, 2003, the Examiner rejected claims 8-17, 19, and 21-24 under 35 U.S.C. § 102(b) as being anticipated by Mehta et al., U.S. Patent No. 4,856,909.

The Examiner stated that "chuck 40 is connected to a drive shaft 12 (col. 4, lines 43-55), which can be used to carry the connected mesh basket. . . . Shaft 12 is in a cylindrical form that would be able to be grasped by a hand, therefore being structurally capable of performing the function of a handle." Applicants traverse this rejection and assert that Mehta et al. does not disclose a handle.

35 U.S.C. § 102(b) states:

A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than a year prior to the date of application for patent in the United States.

Accordingly, a person is not entitled to a patent if the claimed invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than a year prior to the filing date of the U.S. patent application. Claims of a patent application not entitled to a patent under the conditions of 35 U.S.C. § 102(b) are rejected by a Patent Examiner as anticipated by the cited prior art patent or printed publication. A claim is anticipated, however, only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053, (Fed. Cir. 1987). Further, an anticipating prior art patent or printed publication must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized

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by persons of ordinary skill in the field of the invention. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); Diversitech Corp. v. Century Steps, Inc., 850 F.2d 1566, 1567, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988).

Mehta et al. does not disclose, either expressly or inherently, each and every element set forth in the claims. For example, claim 8 requires a lid including a handle on one side of the lid.

In asserting that drive shaft 12 is a handle, the Examiner relied upon a definition of a handle found in Webster's Dictionary, which allegedly states that a handle is "a part that is designed especially to be grasped by the hand" (emphasis added). The Examiner asserted that the cylindrical shape of the drive shaft enables it to be grasped by a hand, and therefore the drive shaft is structurally capable of performing the function of a handle.

Applicants disagree with the Examiner's assertion. Mehta et al. does not disclose or suggest the use of a structure especially designed to be grasped by the hand to allow the user to carry the basket or remove the cover of the basket. The drive shaft 12 disclosed in Mehta et al. is not a handle. Contrary to the Examiner's assertion, the drive shaft is not "designed especially" to be grasped by the hand. Rather, it is designed to rotate relative to inner shaft 14 and rotate the basket 18. As set forth in col. 5, lines 19-22, inner vertical shaft 14 and outer shaft 12 are controllably rotatable one with respect to the other by a conventional drive system 63. Further, as discussed in col. 5, lines 26-31, the central shaft is held fixedly and the hollow outer shaft 12 is rotated. Specifically, Mehta et al. teaches that "in the preferred embodiment shown in the drawings, inner shaft 14 is held fixed to a support while the outer shaft 12 is

rotated." Col. 5, lines 29-31. Since the outer shaft 12 is rotating during use, it follows that it is not "designed especially" to be grasped by the hand as it would rotate in the holder's grasp, and therefore, it cannot be grasped by a hand. In addition, as shown in Figs. 1 and 2 of Mehta et al., at least a portion of drive shaft 12 is inaccessible as it is positioned below the testing medium or solvent 20 of the testing apparatus. Depending on the length of outer shaft 12, in order to have sufficient leverage to maneuver shaft 12 and basket 18 out of container 10, it would be expected for a person to grasp the outer shaft 12 near basket 18 to remove it. Applicants assert that shaft 12 cannot function as a handle because it would require a person to insert his hand into the solvent 20, often an acid, in order to grasp the shaft 12 to remove the basket from the solvent.

Even assuming *arguendo* that the drive shaft 12 was able to be grasped by hand while it is moving, to do so could likely impair the proper operation of the drive shaft. For example, oils and other dirt from the hand could impede proper rotation of the drive shaft. In addition, holding the drive shaft as it rotates could alter the rate of rotation thereby affecting the dissolution rate of the material being tested. Further, using the drive shaft 12 as a handle could cause stresses on shaft 12 itself and on other parts of the basket 18 and chuck 40 that those parts are not designed to withstand, thus potentially causing permanent damage to the device and/or a person attempting to grasp the drive shaft 12.

Independent claim 8 of the present application recites a combination including "a mesh basket configured to receive a material to be tested, and a lid including a handle on one side of the lid." The present invention is intended to be used in various types of testing apparatuses, and to be moved between apparatuses containing different

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solvents. The handle on the lid of the basket facilitates removal of the basket from one apparatus and insertion into a different apparatus.

A handle is defined on page 616 of The American Heritage College Dictionary, (3<sup>rd</sup> ed., 1993), as “[a] part that is designed to be held or operated with the hand.” As stated previously and shown in Figs. 2 and 4 of Mehta et al., does not disclose or suggest a part that is designed to be held or operated with the hand. Instead, Mehta et al. discloses a chuck 40 used to close the container and including three spring clips extending around the lid to engage with slots 32 of end ring 26. Chuck 40 is formed around and connected to horizontal drive shaft 16 via bearing 62 and bevel gear 52. Horizontal drive shaft 16 is in turn connected to inner drive shaft 14 and outer drive shaft 12 via bevel gear 50 and a couple of bearings 60. Mehta et al. is completely silent as to the use of a handle on the lid of its apparatus, and the figures do not disclose or suggest the use of a handle.

Further, there is no motivation for one of ordinary skill in the art to provide Mehta et al. with a handle on its lid. A handle would interfere with the operation of the horizontal drive shaft 16 and outer drive shaft 12, thus rendering Mehta et al.'s apparatus inoperable. Further, a handle on the lid of the basket of Mehta et al. would be inoperable because it could not be reached without a user placing his hand into the testing medium (solvent). Thus, Mehta et al. cannot anticipate or render obvious the invention recited in claim 8.

Finally, the Examiner is incorrect in his assertion that the basket of Mehta et al. may be used with a paddle agitator, continuous flow cell, and rotating basket apparatus. The Examiner refers to col. 1, line 48 - col. 2, line 41 for support for this assertion.

Applicants submit that this discussion, in the background section of the patent, talks about prior art devices and in no way suggests or discloses that the basket of Mehta et al. be used with a paddle agitator, continuous flow cell, or rotating basket apparatus. Mehta et al. discloses a rotating basket apparatus that would not fit within a paddle agitator or continuous flow cell apparatus. Chuck 40 closes the container and includes three spring clips 30 extending around the chuck 40 to engage with slots 32 of end ring 26. Chuck 40 is formed around and connected to horizontal drive shaft 16 via bearing 62 and bevel gear 52. Horizontal drive shaft 16 is in turn connected to inner drive shaft 14 and outer drive shaft 12 via bevel gear 50 and a couple of bearings 60. Drive shaft 12 is connected to a drive system 63. The basket 18 and chuck 40 of Mehta et al. are an integral portion of the testing apparatus of Mehta et al. Unlike the present invention, the basket 18 and chuck 40 of Mehta et al. are not configured or intended to be used with different types of testing apparatus. Mehta et al. does not disclose or suggest use of its device with a paddle agitator or a continuous flow cell. Thus, Mehta et al. cannot anticipate or render obvious claims 13, 14, and 16.

Claims 8-12, 19, 21, and 24 were rejected under 35 U.S.C. § 102(b) as being anticipated by Perkins et al., U.S. Patent No. 4,434,745.

The Examiner stated that Perkins et al. discloses a bird feeder comprising a mesh basket, a lid with a handle on one side and at least one fixing clip on a side of the lid opposite the handle. Applicants traverse this rejection.

Amended claim 8 recites a device "configured to fit within an in vitro substance release testing apparatus, the in vitro substance release testing apparatus being at least one of a paddle agitator, a continuous flow cell, and a rotating basket apparatus, the

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device comprising a mesh basket configured to receive a material to be tested and configured to fit within the substance release testing apparatus, and a lid including a handle on one side of the lid, the handle being configured to permit movement of the mesh basket between testing apparatus."

As set forth in the specification of the present application, in order to fit within various testing apparatus, the dimensions of the mini-basket are substantially smaller than that of a bird feeder. For example, page 4, lines 22-35, of the specification, states that "depending upon the continuous flow cell [type] the maximum height of the mini-basket is 35 or 50 mm." This is approximately two inches in height. In contrast, the bird feeder of Perkins et al., although no specific dimensions are given, is much larger. Perkins et al. teaches, in col. 2, lines 57-60, that "[i]t has been found that gold finches and pine siskins are able to feed from the apparatus according to the invention and prefer to cling to the wire mesh 4 without the need for perches." Applicants submit that any bird feeder sized so as to allow birds to perch on it while feeding is much too large to fit into an in vitro substance release testing apparatus that includes a paddle agitator, a continuous flow cell, and a rotating basket apparatus. For this reason, Perkins et al. cannot anticipate claims 8-12, 19, 21, and 24.

Claims 18 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mehta et al.

The Examiner stated that "Mehta discloses a wire mesh basket discussed above. Mehta does not teach the lid of the basket be made of mesh. It would have been obvious to one of ordinary skill in the art to modify to have a lid that is mesh in order to maximize fluid flowing through the basket."

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Applicants assert that Mehta et al. neither suggests or discloses the invention recited in claims 18 and 20. Claims 18 and 20 each require a lid including a handle on one side of the lid. Mehta et al. does not disclose or suggest the use of a structure especially designed to be grasped by the hand to allow the user to carry the basket or remove the cover of the basket. The drive shaft 12 disclosed in Mehta et al. is not a handle. For at least this reason, Mehta et al. does not disclose or suggest the claimed invention. Reconsideration is requested.


In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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